IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2848
THIS DOCUMENT RELATES TO:	:	
SUE ANN ELMEGREEN	:	
	:	CIVIL ACTION NO. 17-2044
v.	:	
MERCK & CO., INC., et al.	:	

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 372

Bartle, J. August 4, 2021

On May 4, 2017, plaintiff Sue Ann Elmegreen, a citizen of California, brought this lawsuit against Merck & Co., Inc. and Merck Sharp & Dohme Corp. (together, "Merck") in which she claimed that Zostavax, Merck's vaccine intended to counter shingles, caused her to develop shingles. This action is one of six Group A Bellwether Trial Pool Cases selected by the parties for trial in this court as part of Multidistrict Litigation ("MDL") No. 2848.

Plaintiff died on December 23, 2019. On June 18, 2021, Merck moved for summary judgment. First, Merck argues no legal representative has been substituted for the deceased plaintiff so as to allow the continuation of her action. This aspect of the motion is properly characterized as a motion to dismiss, not a motion for summary judgment. See Fed. R. Civ. P.

25(a)(1). Merck also moves for summary judgment on plaintiff's claims for strict liability design defect, failure to warn, and breach of express warranty.[1] Before the court is also the motion of David R. Elmegreen to be substituted for the deceased Sue Ann Elmegreen as the plaintiff under Rule 25 of the Federal Rules of Civil Procedure.

I

The discovery, taken in the light most favorable to the plaintiff, discloses the following. On May 21, 2015, plaintiff was administered Zostavax in accordance with the order of Dr. Ramesh Sinaee. Dr. Sinaee recommended Zostavax to plaintiff in accordance with a guideline from the Centers for Disease Control that patients be vaccinated for shingles upon reaching the age of 60. Plaintiff was 60 years old at the time. She was concerned about shingles which had impacted her mother in her early 80s.

According to plaintiff, Dr. Sinaee told her at the time of ordering Zostavax that there was less than a one percent chance of developing shingles from the vaccine. Plaintiff's decision to obtain the vaccine was based on this information and the impact shingles had on plaintiff's mother in her 80s.

1. Plaintiff does not oppose summary judgment on her claim for strict liability for design defect. There is no such claim under California law. Brown v. Superior Ct., 44 Cal.3d 1049, 1060-62 (Cal. 1988).

Plaintiff testified as follows about her discussion with Dr. Sinaee before she was inoculated with Zostavax:

> **Q.** And other than telling you that the CDC recommends the shingles vaccine at age 60, did you have any other conversation with Dr. Sinaee about the shingles vaccine?
>
> **A.** Yes. She said that less than one percent of people -- she said it's a live virus and she said you can get -- you can actually get shingles from this, however, the research says it's less than one percent of people that develop shingles from the vaccine.
>
> **Q.** And based on that information, you decided that you wanted to get the shingles vaccine; is that right?
>
> **A.** My mother had gotten shingles in her early 80s, I had recalled, and I knew that it was -- that she struggled with that and knowing I had chickenpox - had gotten chickenpox, I -- I -- and I was only 60 -- I was early into the CDC recommendation -- It -- I -- yes.
>
> * * *
>
> **Q.** Based on your experiences, as well as your mother's experience with shingles and Dr. Sinaee's information, that you could get shingles from the shingles vaccine, you decided that you wanted to proceed with the vaccination; is that right?
>
> **A.** That -- The risk level seemed low.
>
> **Q.** And because the risk level seemed low, you decided you wanted to proceed with the vaccination; is that right?
>
> **A.** Yes.

Dr. Sinaee also testified about the conversation:

> **Q.** [Plaintiff] said that people could get shingles from the vaccine in less than one percent of the vaccinations. Do you remember giving her that advice?
>
> **A.** I don't remember if I gave her exact percentages. I -- In general -- In general, I tell people that the chance of getting shingles from the vaccine is low and I -- I also tell people that in my experience, it is not a common occurrence.
>
> * * *
>
> **Q.** And if you found out additional information about the risks and benefits of ZOSTAVAX, you would take that into your risk assessment before prescribing the drug; is that right?
>
> **A.** Correct, yes.
>
> * * *
>
> **Q.** If there are additional risks to the vaccine, you would have wanted to know those before prescribing -- prescribing the vaccine to Ms. Elmegreen; is that right?
>
> **A.** If -- Of course if I had known of a -- of any other serious side effect associated with the vaccine, I would have counseled her.

At the time Dr. Sinaee ordered Zostavax for plaintiff she had not reviewed Merck's prescribing information for Zostavax since "when it first came out . . . I believe it was early 2000." She keeps informed of "changes or updates to pharmaceutical package inserts and prescribing information" for vaccines using Lexicomp, an online medical information tool. Dr. Sinaee does not remember having conversations with any sales

representatives from Merck concerning Zostavax. She does not recall receiving any communications about Zostavax, whether written or in person, from anyone at Merck. She also does not recall receiving, either directly or indirectly, any promotional materials regarding Zostavax from Merck.

As noted above, plaintiff commenced this action on May 4, 2017. On December 6, 2019, the MDL's Plaintiffs' Executive Committee ("PEC") selected this action as one of six bellwether cases initially to proceed through case-specific fact discovery, dispositive motion practice, and a bellwether trial in this court. However, plaintiff died shortly thereafter on December 23, 2019. The PEC informed Merck of plaintiff's death on January 27, 2020 but never designated another action in this MDL to replace it as a Group A Bellwether Trial Pool Case. No party served or filed a statement noting plaintiff's death on the record in accordance with Rule 25(a).

On June 28, 2021, after Merck moved for summary judgment, the PEC filed a Notice of Suggestion of Death. The same day David R. Elmegreen filed a motion for substitution. Mr. Elmegreen stated in a declaration attached to the motion that he is plaintiff's surviving brother and, upon her death, the named trustee of The Sue A. Elmegreen Trust which plaintiff executed on June 21, 2000. In his declaration, Mr. Elmegreen continued that plaintiff conveyed the residue of her estate to

the trust as provided in her will. According to Mr. Elmegreen, there is no proceeding now pending in California for the administration of plaintiff's estate and even in the absence of a will he and his two sisters would be the successors in interest to plaintiff's estate under California's laws of intestate succession. Plaintiff was not married, had no children, and was pre-deceased by her parents.

Mr. Elmegreen attached a certificate of death and plaintiff's will to his declaration. Consistent with his declaration, paragraph "FOURTH" of the will conveys the residue of plaintiff's estate to The Sue A. Elmegreen Trust. Paragraph "FIFTH" appoints Mr. Elmegreen successor trustee in the event of plaintiff's death. No property, tangible or otherwise, is conveyed in the will to any person or entity other than the trust. Mr. Elmegreen also attached to his declaration an extract of the trust agreement for The Sue A. Elmegreen Trust. Just as he stated in his declaration, he is appointed successor trustee in the event of plaintiff's death.

Mr. Elmegreen filed an amended declaration on July 19, 2021 in which he specified that plaintiff's will has not been submitted to probate. He attached a complete copy of the agreement for The Sue A. Elmegreen Trust to the amended declaration.

II

The court first turns to the motion of David R. Elmegreen for substitution. Rule 25(a) provides that "[i]f a party dies and the claim is not extinguished, the court may order substitution of the proper party. A motion for substitution may be made by any party or by the decedent's successor or representative." A motion for substitution must be filed "within 90 days after service of a statement noting the death." Id. Rule 25 sets "a time limit for the motion to substitute based not upon the time of the death, but . . . upon the time information of the death is provided by means of a suggestion of death upon the record." Fed. R. Civ. P. 25 advisory committee's note to 1963 amendment (emphasis added). "Nothing in Rule 25 says that a suggestion of death must be made or sets forth a time frame for doing it." McKenna v. Pac. Rail Serv., 32 F.3d 820, 836 (3d Cir. 1994). If any party "desires to limit the time within which another may make the motion, he may do so by suggesting the death upon the record." Fed. R. Civ. P. 25 advisory committee's note to 1963 amendment.

Merck argues that substitution of a new plaintiff nearly a year and a half after Sue Ann Elmegreen's death is untimely and would be prejudicial. This argument lacks merit. The time that lapsed between plaintiff's death and any substitution is not dispositive of whether the substitution is

timely under Rule 25. Rule 25 requires only that a motion for substitution be filed within 90 days of the date on which a statement noting plaintiff's death was served. It does not specify a time after death by which the statement must be filed or served. See McKenna, 32 F.3d at 836. Mr. Elmegreen timely filed the pending motion for substitution on the same day a statement noting plaintiff's death was entered on the record.

Because of the selection of this action for a bellwether trial in this court, it has proceeded through case-specific fact discovery in accordance with the schedule and procedure set forth in this MDL. Discovery included the deposition of plaintiff before she died. Even if Merck were in some way prejudiced by the delayed substitution, it was free to limit the time for substitution by filing a statement noting her death on the record after Merck learned of it on January 27, 2020. See Fed. R. Civ. P. 25 advisory committee's note to 1963 amendment. Merck cannot now claim prejudice after not having done so.

Merck also asserts that Mr. Elmegreen has failed to establish that he has legal standing to continue this action under the California Code of Civil Procedure. The process to substitute a successor in interest or a legal representative under California law does not apply in federal court. In re Baycol Prod. Litig., 616 F.3d 778, 788 (8th Cir. 2010); see also

U.S. for Use of Acme Granite & Tile Co. v. F.D. Rich Co., 441 F.2d 1143, 1144 (9th Cir. 1971). Although the court looks to California law to determine "who is a proper party for purposes of substitution, . . . how someone, already defined as a 'successor,' should proceed in order to continue a pending action . . . is procedural, and is governed by federal law." In re Baycol Prod. Litig., 616 F.3d at 788. A federal court's decision to permit a representative to be substituted as a plaintiff is a matter of judicial discretion. McKenna, 32 F.3d at 836.

Under California law, "a cause of action for or against a person is not lost by reason of the person's death, but survives subject to the applicable limitations period." Cal. Civ. Proc. Code § 377.20(a). A survival action "may be commenced by the decedent's personal representative or, if none, by the decedent's successor in interest." Cal. Civ. Proc. Code § 377.30 (emphasis added).

A "'decedent's successor in interest' means the beneficiary of the decedent's estate or other successor in interest who succeeds to a cause of action or to a particular item of the property that is the subject of a cause of action." Cal. Civ. Proc. Code § 377.11. "Where a cause of action is prosecuted on behalf of an express trust, the trustee is the real party in interest because the trustee has legal title to

the cause." Saks v. Damon Raike & Co., 8 Cal. Rptr. 2d 869, 874 (Cal. Ct. App. 1992); see also Cal. Civ. Proc. Code § 369.

Mr. Elmegreen's declarations, together with plaintiff's will and trust agreement, satisfy the court that he is the trustee of The Sue A. Elmegreen Trust to which this action has succeeded. As trustee, he has legal title to the action, is the real party in interest, and may continue it on behalf of the trust. See Saks v. Damon Raike & Co., 8 Cal.Rptr. 2d at 874; see also Cal. Civ. Proc. Code § 369(a)(2).

Accordingly, the court will grant the motion of David R. Elmegreen, as trustee of The Sue A. Elmegreen Trust, to be substituted as the plaintiff and to continue this action in her stead. The court will deny the motion of Merck to dismiss (incorrectly denominated as a motion for summary judgment) for failure to substitute a legal representative for the deceased plaintiff Sue Ann Elmegreen.

III

Merck moves for summary judgment on plaintiff's claims for failure to warn and for breach of express warranty under California law.

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P.

56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A factual dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is material if it might affect the outcome of the suit under governing law. Id. at 248.

We view the facts and draw all inferences in favor of the non-moving party. See In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004). "The mere existence of a scintilla of evidence in support of the [non-moving party]'s position will be insufficient; there must be evidence on which the jury could reasonably find for [the non-moving party]." See Anderson, 477 U.S. at 252. "The plaintiff must present affirmative evidence in order to defeat a properly supported motion for summary judgment." Id. at 257. If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact, the court may consider the fact undisputed for purposes of summary judgment. Fed. R. Civ. P. 56(e).

IV

Merck moves for summary judgment on the plaintiff's claims for failure to warn on the ground that plaintiff has not presented evidence to establish that the physician who ordered Zostavax for Sue Ann Elmegreen would have changed her

prescribing decision if Merck had provided a different warning of shingles risk.[2]

Under California law, drug manufacturers are strictly liable for injuries caused by their failure to give warning of dangers that were known or scientifically knowable at the time they manufactured and distributed the drug. Carlin v. Superior Ct., 56 Cal.Rptr.2d 162, 163-64 (Cal. 1996). A manufacturer may also be held liable under a theory of negligence if it "did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." Id. at 166.

To succeed on a claim for failure to warn, a plaintiff must establish that the inadequacy or the absence of a warning caused the plaintiff's injury. Motus v. Pfizer Inc., 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), aff'd Motus v. Pfizer Inc., 358 F.3d 659 (9th Cir. 2004). California law applies the learned intermediary doctrine in actions for personal injury arising from the use of prescription drugs, that is, "in the case of prescription drugs, the duty to warn runs to the

2. Merck moves for summary judgment on plaintiff's "failure-to-warn claims" without drawing a distinction between the claim for negligent failure to warn and the claim for strict liability failure to warn. The two claims are distinct. See Carlin v. Superior Ct., 56 Cal.Rptr.2d 162 (Cal. 1996). Because Merck seeks summary judgment for lack of causation, which is a requirement of both causes of action, the court will discuss the claims together.

physician, not to the patient." Carlin, 56 Cal.Rptr.2d at 170 (emphasis original). A plaintiff asserting "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." Motus, 358 F.3d at 661. The burden is on the plaintiff "to show that stronger warnings would have changed [plaintiff]'s medical treatment or averted [the injury]." Id.

Dr. Sinaee told Sue Ann Elmegreen that the risk of Zostavax causing shingles was low — less than one percent pursuant to Ms. Elmegreen's recollection. Dr. Sinaee testified that had she known of additional risks of Zostavax she would have taken them into account in making her prescribing decision and would have counseled Ms. Elmegreen. Ms. Elmegreen testified that she was worried about the shingles which had impacted her mother in her 80s. She agreed to be inoculated with Zostavax in light of the low risk that it would cause shingles as that risk was understood and shared with her by Dr. Sinaee.

The evidence is sufficient to draw a reasonable inference that if the likelihood of contracting shingles from Zostavax was greater than what Dr. Sinaee understood it to be, she would have shared it with Ms. Elmegreen, who, if the amount of the additional risk was significant, would not have agreed to receive the vaccine. The likelihood of contracting shingles

from Zostavax and whether that likelihood was great enough to alter Ms. Elmegreen's decision to receive the vaccine are disputed factual matters appropriately presented to the jury.

In addition, Merck argues plaintiff's claim for breach of express warranty fails as a matter of law because plaintiff has presented no evidence that the prescribing physician relied on an affirmation of fact or promise from Merck in deciding to prescribe Zostavax to Ms. Elmegreen. Liability for breach of express warranty requires that the defendant: "(1) made an affirmation of fact or promise or provided a description of its goods; (2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff." Tae Hee Lee v. Toyota Motor Sales, U.S.A., Inc., 992 F. Supp. 2d 962, 978 (C.D. Cal. 2014) (emphasis added). Under California law, privity of contract is not a requirement to succeed on a claim for breach of express warranty "where the purchaser of a product relied on representations made by the manufacturer in labels or advertising material." Burr v. Sherwin Williams Co., 42 Cal. 2d 682, 696 (Cal. 1954).

The learned intermediary doctrine also applies to claims for breach of warranty arising from prescription drugs. Carlin, 56 Cal.Rptr.2d at 170. Therefore, the crux of a claim for breach of express warranty arising from the use of a

prescription drug is the breach of an affirmation of fact, promise, or product description expressly communicated by the defendant-manufacturer to the prescribing doctor. See Tae Hee Lee, 992 F. Supp. 2d at 978; see also Carlin, 56 Cal.Rptr.2d at 170. This differs from a failure to warn claim where liability is premised on a manufacturer's failure to communicate a known or knowable risk to the prescribing doctor. Carlin, 56 Cal.Rptr.2d at 163-64.

Dr. Sinaee does not remember having any conversations with a Merck representative concerning Zostavax. She does not remember ever receiving any communications or promotional materials, whether verbal or written, from anyone at Merck regarding Zostavax. Further, she did not read the updated label for Zostavax before prescribing it to Ms. Elmegreen.

To support its claim for breach of express warranty, the plaintiff appears to rely generally on Dr. Sinaee's testimony that she reviewed the label for Zostavax "when it first came out" and kept informed of changes to vaccines using the online medical information tool Lexicomp. Significantly, plaintiff does not detail in its papers exactly what express Merck affirmation of fact, promise, or description on which Dr. Sinaee relied to prescribe Ms. Elmegreen Zostavax. As such, it fails to present any affirmative evidence directly addressing

Merck's motion for summary judgment on this issue. See Anderson, 477 U.S. at 257.

For these reasons, the court will deny the motion of Merck for summary judgment on plaintiff's claims for failure to warn. The court will grant the motion of Merck for summary judgment on plaintiff's claim for breach of express warranty.